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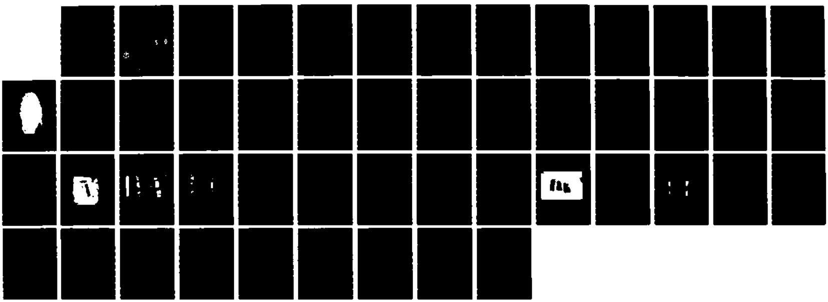

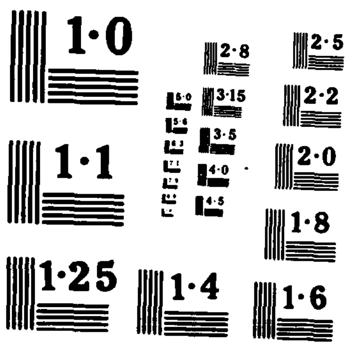
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Report No. 86-1

FIELD DEVELOPMENTAL TEST OF THE DUAL BARREL AUTOMATIC INJECTOR MARK II

May 1986

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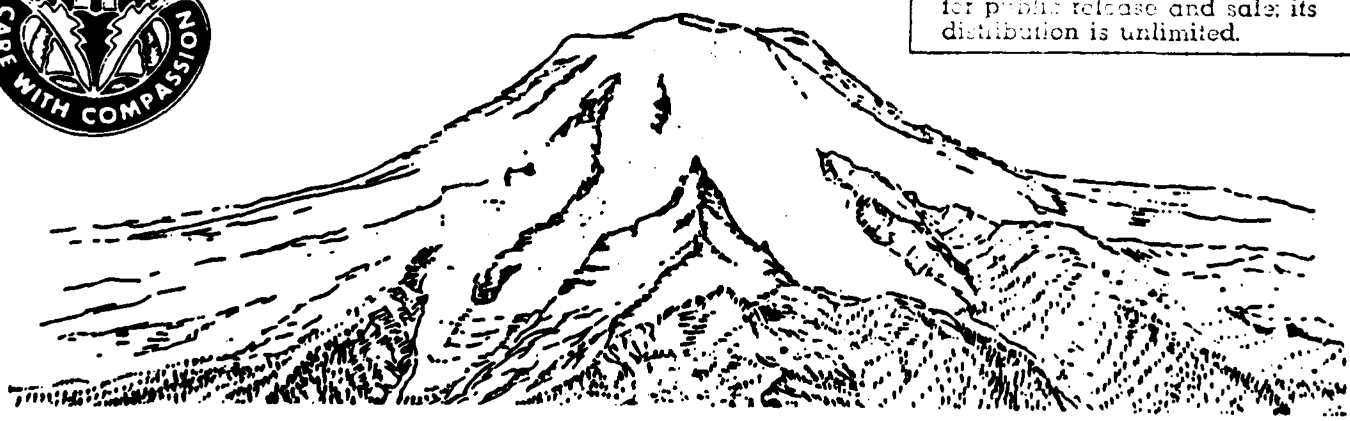

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autoinjector; injector; field test; drug delivery system; nerve agent antidote; chemical defense; medical equipment; atropine; pralidoxime

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

The Dual Barrel Autoinjector System, MARK II, is a two barrel, nose-activated automatic injector system that delivers the contents of both barrels intramuscularly with a single action by the user. The MARK II injector was conceived as a candidate replacement of the currently fielded MARK I.

Field developmental tests were conducted on 1920 prototype injectors randomly drawn from production. Sixty injectors were

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retained at Fort Detrick, MD, as reference controls (RC), sixty were drawn from 1860 injectors after shipment to Fort Lewis, WA as shipping controls (SC), and the remaining 1800 injectors were distributed to 600 soldiers of an Infantry brigade, and subjected to field conditions (FT).

Each soldier was instructed to carry three injectors in a small arms ammunition pouch on their load bearing suspenders for 18-21 days of field training in dry hot conditions at Yakima Firing Center, WA. Following this exposure, the injectors were reinspected, repackaged and sent to USAMBRDL, Fort Detrick, MD where each injector was tested for firing rate, force, injection volumes and needle lengths.

Out of 1525 injectors actually tested (FT), 46 (3.0%) were found to have a malfunction characterized by the atropine barrel sliding forward in the casing. One or more such malfunctions occured in 5.9% of the injector sets carried by soldiers in the field. The malfunction released the atropine barrel from the safety mechanism and this barrel could then fire with random contact. This occured in ten of the 46 cases. The malfunction was not observed for any of the 120 control injectors and it was specifically associated with soldiers whose principal activity involved motorized travel or the operation of heavy engineering equipment in the rough field terrain.

Functional testing at USAMBRDL revealed additional defects not specifically associated with field exposure. The defects which could significantly affect performance of the injector included deficient atropine barrel volumes (3.7%), excessive activation forces (5.9%), and loose safety pins (11.0%) in the FT injectors. A similar incidence was observed for each of these defects in the SC and RC injectors.

Most soldiers interviewed at the end of the test found that the location of the injectors was suitable and convenient. Other soldier suggestions and reactions are included in the report.

The results of this test underscore the importance of testing new equipment under realistic field conditions and in the hands of the end users.

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DEFINITION OF TERMS

ATROPINE BARREL - the smaller green-tipped cylinder contained within the autoinjector housing

CROSSTABULATION - a two-way (by two variables) breakdown of frequency

DEFECT - [synonymous with "malfunction"]

FREQUENCY - number of times (or percentage) that an occurrence is repeated in a given range

INCIDENCE - the degree of occurrence, given as a percentage of the sample examined

MALFUNCTION - failure to function according to predetermined test criteria

OCCURRENCE - a detected event

2-PAM-CL BARREL - the larger black-tipped cylinder contained within the autoinjector housing

SAFETY PIN - the yellow plastic protrusion from the safety cap which prevents injector activation

SAFETY SCREW - the metal screw which attaches the safety pin to the cap

ACKNOWLEDGMENTS

SP4 George Camacho managed the injector set inventory and he and SGT John Robbins performed the soldier interviews. Mr. Troy Patience performed the data reduction. 1LT Andrew Ramotnik successfully achieved the tasking of a unit for the test and CPT Ray Coats coordinated the test at the unit level. Mr. John Hodge effected the functional tests at USAMBRDL.

BACKGROUND

The need for a dual injection system to separately deliver the two components of the currently used nerve agent antidote was determined from studies which indicate that pralidoxime chloride (2-PAM-Cl) reduces the speed of action of atropine sulfate when the two agents are administered at the same site (Sidell et.al. 1970). This delay in atropine action (with activity measured on the basis of heart rate) following intramuscular injection is attributed to a slowed absorption caused by mixing with solutions of higher osmolarity (Sidell, 1974). In the absence of an alternate combination of antidotes which is at least equally effective, a system which separates the two drugs is required.

The Dual Barrel Autoinjector System, MARK II, is a nose-activated automatic injector system which delivers the contents of two separate barrels through two separate needles, intramuscularly, with a single action by the user. The MARK II injector was conceived as a candidate replacement of the currently fielded Nerve Agent Antidote Kit, MARK I. The MARK I is composed of two single barrel automatic injectors, each of which is fired independently. The MARK II injector was envisioned as a device comparable to the MARK I in safety, reliability, and efficacy but easier to use than the MARK I (Jacob, 1985).

A field developmental test of the MARK II was contracted between the U.S. Army Medical Materiel

Development Activity (USAMMDA) and Madigan Army Medical Center (MAMC) in order to determine the reliability of the product in the hands of soldiers in a field environment. The U.S. Army Medical Bioengineering Research and Development Laboratory (USAMBRDL) was tasked to perform specific engineering tests on the product and on the field tested injectors. Concurrent with these studies, other agencies were to be involved in the testing of the theoretical operational advantage of the MARK II over the MARK I. As another aspect of the field developmental test, opinions of the soldiers who carried the injectors were solicited concerning the most convenient carrying location for the injectors and their reactions to carrying them.

References

Jacob, W.H. (1985). Test Plan, Field Developmental Test of Dual Barrel Automatic Inector, MARK II. USAMMDA, Fort Detrick, MD.

Sidell, F.R. (1974). Modification by Diluents of Effects of Intramuscular Atropine on Heart Rate in Man. Clin Pharmacol Ther 16(4): 711-715.

Sidell, F.R., Magness, J.S., Bollen, T.E. (1970). Modification of the Effects of Atropine on Human Heart Rate by Pralidoxime. Clin Pharmacol Ther 11(1): 68-76.

MATERIALS & METHODS

1. The Autoinjectors. Fully functional prototype injectors (1,920) were delivered by the manufacturer (Survival Technology, Inc., Bethesda, MD) to USAMMDA. These were identical to a functional MARK II injector in every respect except for the substitution of placebo for the actual drugs. The placebo in the 2-PAM-Cl barrel consisted of 18 mg sodium chloride, 2 mg methylparaben, 0.2 mg propylparaben and water (total volume: 2 ml). The placebo in the atropine barrel consisted of 12.5 mg glycerin, 3.0 mg sodium citrate, 2.8 mg phenol, 2.0 mg citric acid and water (total volume: 0.7 ml).

2. Control Injectors. Sixty injectors were selected at random to remain at USAMMDA as reference controls (RC) and the remainder was shipped to MAMC in the original cartons (composed of 2 outer containers) used by the manufacturer. After shipping, sixty injectors were selected at random to remain at MAMC as shipping controls (SC) and the remaining injectors were distributed for the field test. All injectors were individually inspected for externally detectable abnormalities before distribution.

3. Field Test Issue. Eighteen hundred injectors were distributed to 600 soldiers one to five days before their departure from Fort Lewis by convoy to Yakima Firing Center (Washington). Three injectors were issued to each soldier by injector serial number and matched to a personal data

summary (sample hand receipt at Appendix A-1). Soldiers received these three injectors placed with the nose downward in a small arms ammunition pouch and they were instructed to carry the injectors on the front, right side of their web belts as part of their standard load (Figure 1). This equipment was required to be with them at all times in the field.

4. Command & Control of Issue. Participation in the project was enacted by a formal tasking through Headquarters I-Corps Fort Lewis. The distribution of injectors within a tasked brigade was then dictated by the brigade commander. The method of issue and control of injectors at these unit levels was individually controlled by unit commanders within certain guidelines essential for the test and IAW the test safety release (FORSCOM SAB, 7 Sept 85). Each unit commander or representative was informed of the purpose of the test and instructed to ensure that their soldiers carried the injectors in the ammunition pouches on the front, right side of their web belts at all times, exposing them to field conditions without additional special protection. Tampering was to be minimized and accountability was emphasized by the threat of punitive actions for clear tampering and a fifty dollar assessment per lost injector.

Figure 1. Typical location of the small arms ammunition case with injectors carried by a test participant.

5. Test Participants. The following pattern of distribution within a tasked light infantry brigade was designated by the commander:

	SOLDIERS	INJECTORS
a. brigade headquarters company	110	330
b. engineer company	80	240
c. air defense artillery company	80	240
d. field artillery battalion	80	240
e. military intelligence company	50	150
f. infantry battalion		
1) headquarters company	20	60
2) company A	50	150
3) company B	50	150
4) company C	50	150
5) combat support company	30	90
	600	1800

6. Collection of Injectors. After approximately three weeks of exposure to field conditions in Yakima, the injectors were collected, their gross external condition was noted on the original handreceipt form, and as many soldiers as possible were interviewed (sample questionnaire at Appendix A-2). A special effort was made to interview all soldiers returning obviously damaged or fired injectors. Injectors were collected on the last two days at Yakima from three of the units (engineers, air defense artillery and field artillery) and as many of these soldiers as possible were interviewed on the spot. Injectors from the other three units were returned to the investigators within three days of their return to Fort Lewis. No punitive actions were taken or fines levied since it became clear that the majority of soldiers were returning untampered injectors.

7. Reinspection and Shipment of Injectors. The injectors were reexamined at MAMC and an inspection checklist was completed for each one (sample checklist at Appendix A-3). These were then repackaged in their original double carton configuration and returned to Fort Detrick, MD by commercial transport. The malfunctioned injectors (fired and clearly damaged injectors) and additional injectors which had not been carried in the field nor retained as shipping controls were returned in the same shipment but wrapped in more protective packing materials.

8. Engineering Tests. At USAMBRDL all injectors other than the already identified malfunctions were tested for the force necessary to fire the armed injector, firing rate, injection volumes and post firing needle lengths. This data was recorded against injector serial number and returned to MAMC for data reduction along with the information previously collected.

9. Data Analysis. Data was assembled by injector serial number from the personal data sheet, the injector checklist, and the engineering test data sheets. This set was analyzed with frequency outputs, including an adjusted frequency which exluded missing, untested or undefined data points. Military occupational specialty (MOS) categories were collapsed to the principal categories of career management fields (CMF). Variables such as CMF and type of unit were then examined in a crosstabulation procedure (with chi-

squared analysis) to test for differences in the incidence of specific injector malfunctions. Injectors with gross damage or malfunction (e.g. one needle protruding) were pinpointed and further defined in terms of interview and personal data. Interview responses were also categorized and reported in a descriptive manner.

10. <u>Criteria for Injector Malfunctions</u>:

a. any injector with one or both needles fired and with safety cap still in place;

b. any injector capable of being fired with an axial load of 20-22 pounds with the safety cap still in place;

c. any injector which requires outside of 2.0-8.0 pounds of activation force after removal of the safety cap;

d. any injector which discharges volumes outside of 0.63-0.77 mls from the atropine barrel or outside of 1.8-2.2 mls from the 2-PAM-Cl barrel;

e. any injector which completes volume discharge in greater than 4.0 seconds;

f. any injector which has an exposed needle length outside of 0.75-0.88 inches from the atropine barrel or outside of 0.71-0.91 inches from the 2-PAM-Cl barrel;

g. any injector which is cracked, contains loose parts, or appears to have leaked.

RESULTS

1. Characteristics of Test Participants. Nearly half of the injector sets tested in this study were carried by soldiers below the rank of Sergeant and less than 10% of soldier-tested sets were carried by ranks above Sergeant First Class (Table 1).

Table 1. Rank Associated with Injector Sets Tested.

Rank	Absolute Frequency (# sets)	Relative Frequency (percent)	Adjusted Frequency (percent)	Cumulative Frequency (percent)
Enlisted				
PV1-PV2	86	13.4	15.1	17.9
PFC	124	19.4	21.7	36.8
CPL/SP4	172	26.9	30.1	66.9
SGT	86	13.4	15.0	81.9
SSG	34	5.3	6.0	87.9
SFC	23	3.6	4.0	91.9
1SG/MSG	5	0.8	0.9	92.8
SGM/CSM	2	0.3	0.3	93.1
Officer				
WO1-CPT	35	5.5	6.2	99.3
MAJ-COL	4	0.6	0.7	100.0
Undefined/ Control sets	69	10.8	excluded	100.0
Total	640	100.0	100.0	

Over one third of the enlisted soldiers defined by MOS were infantrymen (Career Management Field 11 series). Another third were categorized in air defense artillery, field artillery and combat engineering CMFs (Table 2).

At the end of the test, it became clear that the soldiers' attitudes and the degree of test compliance reflected differences in how they had been briefed at their

Table 2. Principal Job Specialties of Enlisted Participants.

Career Management Field	Absolute Frequency (number)	Relative Frequency (percent)	Adjusted Frequency (percent)
11 - Infantry	173	34.2	37.5
16 - Air Defense Artillery	58	11.5	12.6
13 - Field Artillery	57	11.3	12.4
12 - Combat Engineering	49	9.7	10.6
31 - Communications	39	7.7	8.5
96 - Military Intelligence	24	4.7	5.2
63 - Mechanical Maintenance	21	4.2	4.6
76 - Supply	18	3.6	3.9
62 - Construction	14	2.8	3.0
54 - Chemical	8	1.6	1.7
Others with a defined MOS	44	8.7	excluded
Total	505	100.0	100.0

unit level. Table 3 summarizes the number of injectors actually field tested by each unit. This number is derived as the difference of injectors originally distributed to each unit and number which were lost, came back clean (no visible wear or dust on the wrapper), or were deliberately fired (explained in notes on Unit 6 characteristics, below).

Table 3. Number of Injectors Tested by Unit (number of affected sets are given in parentheses).

Unit	Distributed	Lost	Fired	Clean	Difference
1	330 (110)	3 (1)	0	126 (42)	201 (67)
2	240 (80)	0	0	3 (1)	237 (79)
3	240 (80)	0	0	54 (18)	186 (62)
4	240 (80)	3 (1)	0	12 (4)	225 (75)
5	150 (50)	3 (1)	0	3 (1)	144 (48)
6	600 (200)	6 (2)	8 (6)	54 (18)	532 (174)
Tot	1800 (600)	15 (5)	8 (6)	252 (84)	1525 (505)

Unit 1. There were fewer soldiers in the brigade headquarters company than the number of injectors distributed to them. Consequently, 28 sets remained locked up in the unit NBC supply room and were not field tested. Most of the others were carried by headquarters staff who remained stationary in a relatively clean and quiet field environment. The distribution of the injectors was controlled by the NBC specialist.

Unit 2. The engineering company was briefed by the company executive officer as to the purpose of the test and the soldiers were instructed not to handle the injectors. The injectors were not demonstrated for the soldiers. In the field, each soldier was inspected twice per day to see that the injectors were carried according to instructions. Soldiers in this unit were exposed to rigorous field training (e.g. low crawling with live fire nearby); some also operated construction equipment.

Unit 3. Injectors were individually handreceipted to soldiers of the air defense artillery company by test support personnel. The commander was a chemical officer with a clear understanding of the goals of the test; he chose to brief his company at a later formation and included at least one demonstration of the injector. In the field this unit test-fired ADA weapons and was also subjected to rigorous ground training. At the field collection site several of the soldiers admitted to the two specialists assisting in the test that they had packed their injectors

away in their rucks or duffel bags. Several left them in wall lockers at Fort Lewis. They claimed to be concerned about the risk of accidental injection from the MARK-II device and they vividly recalled the commander's demonstration as a forceful pop (against a piece of cardboard) with the contents arcing through the air for a considerable distance.

Unit 4. During the training exercise, the field artillery unit (fire support and headquarters battery) split into many small teams of two to five men and were transported to points across the full range of the area of operation. The distribution of injectors was coordinated by the executive officer of the battalion and he effectively tasked a lieutenant to control and monitor the testing.

Unit 5. Injectors were individually handreceipted to soldiers in the military intelligence unit by test support personnel. The soldiers were allowed to examine a fired injector. The commander briefed them to carry them and not to handle them. The function of this unit in the field called for relatively clean and stationary work.

Unit 6. The infantry battalion supply NCO was assigned the task of distributing injectors to the company level. He did this through the company NBC specialists (MOS 54E) who were briefed by him on the purpose of the test and threatened with a $50 charge for each fired or lost injector. During the field exercise, HHC and A Company played a

supporting/logistical role; B and C Company underwent rigorous infantry field training; the scouts handled mortars and did a lot of driving. Each of five infantry soldiers who returned an injector with safety cap displaced and both barrels fired acknowledged that this was the result of a deliberate action. A sixth soldier, returning all three normally fired, stated that he was "just walking along when all three fired off and injected him in the [buttocks]". There was no proof, medical or otherwise, to give credence to this claim and this was also categorized as a "deliberate fire" as opposed to a "malfunction".

All soldiers were exposed to dry hot dusty field conditions.

2. Functional Testing after Field Exposure. The frequency distributions of the results of the USAMBRDL engineering tests are shown for injector activation forces (Table 4), volumes discharged from the atropine barrel (Table 5), volumes discharged from the 2-PAM-Cl barrel (Table 6), and times to complete discharge (Table 7). There were no discrepancies noted for needle lengths and these were not further quantified; however, needles were missing altogether from the atropine barrel in two injectors. There were no firings reported with axial loading of 20-22 pounds for any injectors with safety caps in place.

The force required to activate the injector was excessively high in 5.3% of the tested sample and this was differently distributed within units and CMFs (Table 8).

Table 4. Frequency Distribution of Injector Activation Forces.

Force (pounds)	Absolute Frequency (number)	Relative Frequency (percent)	Adjusted Frequency (percent)	Cumulative Frequency (percent)
below specifications				
< 0.5	2	0.1	0.1	0.1
0.5 - 1.0	1	0.1	0.1	0.2
1.0 - 1.5	0	0.0	0.0	0.2
1.5 - 2.0	0	0.0	0.0	0.2
within specifications				
2.0 - 2.5	0	0.0	0.0	0.2
2.5 - 3.0	2	0.1	0.1	0.3
3.0 - 3.5	17	0.9	0.9	1.2
3.5 - 4.0	94	4.9	5.2	6.4
4.0 - 4.5	167	8.7	9.2	15.6
4.5 - 5.0	304	15.8	16.8	32.4
5.0 - 5.5	358	18.7	19.8	52.2
5.5 - 6.0	319	16.6	17.6	69.8
6.0 - 6.5	177	9.2	9.8	79.6
6.5 - 7.0	140	7.3	7.7	87.3
7.0 - 7.5	72	3.7	4.0	91.3
7.5 - 8.0	63	3.3	3.5	94.8
above specifications				
8.0 - 8.5	16	0.8	0.9	95.7
8.5 - 9.0	26	1.4	1.4	97.1
9.0 - 9.5	14	0.7	0.8	97.9
9.5 - 10.0	34	1.8	1.9	99.8
10.0 - 10.5	2	0.1	0.1	99.9
10.5 - 11.0	1	0.1	0.1	100.0
not measured	110	5.7	excluded	
Total	1920	100.0	100.0	

Mean force = 5.96 lbs
Std Dev = 0.067 lbs

95% Confidence Interval = 5.83 - 6.09 lbs

Test sample below specifications = 3 (0.2%)
Test sample above specifications = 93 (5.1%)

Total sample outside of specifications = 96 (5.3%)

Table 5. Frequency Distribution of Volumes Discharged from Atropine Barrel (green tip).

Volume (mls)	Absolute Frequency (number)	Relative Frequency (percent)	Adjusted Frequency (percent)	Cumulative Frequency (percent)
below specifications				
0.12 - 0.35	4	0.2	0.2	0.2
0.35 - 0.41	4	0.2	0.2	0.4
0.41 - 0.45	2	0.1	0.1	0.5
0.45 - 0.49	3	0.2	0.2	0.7
0.49 - 0.53	9	0.5	0.5	1.2
0.53 - 0.57	9	0.5	0.5	1.7
0.57 - 0.59	13	0.7	0.8	2.5
0.59 - 0.61	9	0.5	0.5	3.0
0.61 - 0.63	6	0.3	0.3	3.3
within specifications				
0.63 - 0.65	32	1.7	1.9	5.2
0.65 - 0.67	23	1.2	1.3	6.5
0.67 - 0.69	22	1.1	1.3	7.8
0.69 - 0.71	318	16.6	18.6	26.4
0.71 - 0.73	1074	55.8	62.8	89.2
0.73 - 0.75	114	5.9	6.7	95.9
0.75 - 0.77	45	2.3	2.6	98.5
above specifications				
0.77 - 0.79	7	0.4	0.4	98.9
0.79 - 0.81	3	0.2	0.2	99.1
0.81 - 0.83	5	0.3	0.3	99.4
0.83 - 0.85	3	0.2	0.2	99.6
0.85 - 0.87	1	0.1	0.1	99.7
0.87 - 0.89	1	0.1	0.1	99.8
0.89 - 0.91	1	0.1	0.1	99.9
0.91 - 0.93	1	0.1	0.1	100.0
not measured	211	10.9	excluded	
Total	1920	100.0	100.0	

Mean volume = 0.725 mls
Std Dev = 0.045 mls

95% Confidence Interval = 0.637 - 0.813 mls

Test sample below specifications = 59 (3.4%)
Test sample above specifications = 22 (1.3%)

Total sample outside of specifications = 81 (4.7%)

Table 6. Frequency Distribution of Volumes Discharged from 2-PAM-Cl Barrel (black tip).

Volume (mls)	Absolute Frequency (number)	Relative Frequency (percent)	Adjusted Frequency (percent)	Cumulative Frequency (percent)
below specifications				
0.0	2	0.1	0.1	0.1
0.2 - 0.4	3	0.2	0.2	0.3
0.4 - 0.6	0	0	0	0.3
0.6 - 0.8	1	0.1	0.1	0.4
0.8 - 1.0	0	0	0	0.4
1.0 - 1.2	1	0.1	0.1	0.5
1.2 - 1.4	1	0.1	0.1	0.6
1.4 - 1.6	1	0.1	0.1	0.7
1.6 - 1.8	8	0.4	0.5	1.2
within specifications				
1.80 - 1.85	8	0.4	0.5	1.7
1.85 - 1.90	54	2.8	3.2	4.9
1.90 - 1.95	324	16.9	19.0	23.9
1.95 - 2.00	673	35.0	39.4	63.3
2.00 - 2.05	606	31.6	35.5	98.8
2.05 - 2.10	17	0.9	0.9	99.7
above specifications				
2.10 - 2.15	5	0.3	0.3	100.0
not measured	214	11.1	excluded	
Total	1920	100.0	100.0	

Mean volume = 1.97 mls
Std Dev = 0.093 mls

95% Confidence Interval = 1.78 - 2.15 mls

Test sample below specifications = 17 (1.0%)
Test sample above specifications = 5 (0.3%)

Total sample outside of specifications = 22 (1.3%)

Table 7. Frequency Distribution of Times to Complete Discharge.

Time (secs)	Absolute Frequency (number)	Relative Frequency (percent)	Adjusted Frequency (percent)	Cumulative Frequency (percent)
within specifications				
< 1.0	1	0.1	0.1	0.1
1.0 - 1.1	4	0.2	0.2	0.3
1.1 - 1.2	10	0.5	0.6	0.9
1.2 - 1.3	31	1.6	1.7	2.6
1.3 - 1.4	49	2.5	2.7	5.3
1.4 - 1.5	65	3.4	3.6	8.9
1.5 - 1.6	153	8.0	8.5	17.4
1.6 - 1.7	195	10.1	10.8	28.2
1.7 - 1.8	370	19.3	20.6	48.8
1.8 - 1.9	304	15.8	16.9	65.7
1.9 - 2.0	299	15.6	16.6	82.3
2.0 - 2.1	185	9.6	10.3	92.6
2.1 - 2.2	84	4.4	4.6	97.2
2.2 - 2.3	22	1.1	1.2	98.4
2.3 - 2.4	16	0.8	0.9	99.3
2.4 - 2.5	3	0.2	0.2	99.5
2.5 - 2.6	1	0.1	0.1	99.6
2.6 - 2.7	4	0.2	0.2	99.8
2.7 - 2.8	2	0.1	0.1	99.9
2.8 - 2.9	1	0.1	0.1	100.0
above specifications				
>4.0	0	0.0	0.0	
not measured	121	6.3	excluded	
Total	1920	100.0	100.0	

Mean time to complete discharge = 1.80 secs
Std Dev = 0.226 secs

95% Confidence Interval = 1.36 - 2.24 secs

Test sample below specifications = n/a
Test sample above specifications = 0

Total sample outside of specifications = 0

Table 8. Crosstabulation of Injectors Outside of Specifications, Compared by Unit, Rank, and CMF.*

Category	Force High	Atropine barrel Low	Atropine barrel High	2-PAM barrel Low
UNIT				
1 BDE HHC	17 (9.0)	5 (2.8)	1 (0.6)	1 (0.6)
2 ENGR	8 (3.6)	7 (3.2)	3 (1.4)	1 (0.5)
3 ADA	23 (11.7)	4 (2.1)	3 (1.3)	0
4 FA	26 (12.2)	13 (6.5)	3 (1.5)	3 (1.5)
5 MI	9 (6.6)	3 (2.2)	0	1 (0.7)
6 INF	5 (1.0)	20 (4.1)	15 (3.1)	9 (1.9)
Signif level	$p < 0.01$	$p = 0.15$		$p = 0.32$
RANK				
PV1-PFC	25 (4.6)	21 (4.2)	13 (2.6)	9 (1.8)
SP4	20 (4.5)	12 (2.8)	6 (1.4)	3 (0.7)
SGT-SSG	28 (9.2)	14 (4.8)	1 (0.3)	2 (0.7)
SFC-SGM	6 (8.0)	1 (1.5)	3 (4.4)	1 (1.5)
WO1-COL	9 (8.3)	4 (3.8)	1 (1.0)	0
Signif level	$p = 0.13$	$p = 0.15$		$p = 0.33$
CMF				
11 Inf	4 (0.9)	17 (4.1)	15 (3.6)	8 (1.9)
16 ADA	17 (12.7)	2 (1.6)	1 (0.8)	0
13 FA	20 (13.1)	10 (7.1)	2 (1.4)	1 (0.7)
12 Engr	4 (2.8)	5 (3.6)	3 (2.2)	1 (0.7)
31 Commo	6 (6.5)	3 (3.3)	0	2 (2.3)
96 MI	8 (12.5)	3 (4.8)	0	0
63 Mech	4 (8.2)	1 (2.1)	1 (2.1)	1 (2.1)
76 Supply	2 (4.9)	1 (2.5)	0	0
62 Constr	1 (2.9)	0	0	0
54 Chem	2 (8.3)	0	0	0
Other	32 (7.9)	13 (9.2)	3 (2.1)	2 (0.5)
Signif	$p < 0.01$	$p = 0.13$		$p = 0.54$

* injectors not exposed to field conditions are excluded from this summary; percentage of the tested sample is given in parentheses

Volumes discharged from the atropine barrel were out of the specified ranges in both direction for a non-trivial proportion of the injectors tested (4.7%). The volumes measured ranged from 0.12 to 0.93 mls (Table 5).

Volumes discharged from the 2-PAM-Cl barrel were within specifications except for a relatively small proportion of the samples. Most of these discrepancies were for deficient volumes and these reportedly extended all the way down to zero volume (Table 6). Several of these injectors were noted to have broken ampules in the 2-PAM-Cl barrel.

The times to complete discharge were well within specifications and all injectors which fired did so in less than 2.9 seconds (Table 7).

3. <u>Malfunctions in Control and Field Tested Injectors</u>. Within the first week of field exposure it become apparent that a significant failure of the safety mechanism could occur. The atropine barrel slides forward, probably by escaping two small plastic retaining pins, and in this condition it is capable of firing (Figures 2 & 3). In five sequential trials it was observed that relatively light pressure on one of these loose atropine barrel injectors would cause the needle on that side to fire and the volume to discharge. The 2-PAM-Cl barrel remains inactivated and the safety cap is still firmly seated (Figure 4). Several injectors fired in this way and needles came through the bottoms of ammunition pouches as they were being carried by soldiers.

Figure 2. An example of the principal injector malfunction displayed by a soldier in the field. A single needle protrudes from the atropine barrel. This occurred with the safety cap in place. The needle appeared through the bottom of the carrying pouch while the soldier was driving over rough terrain.

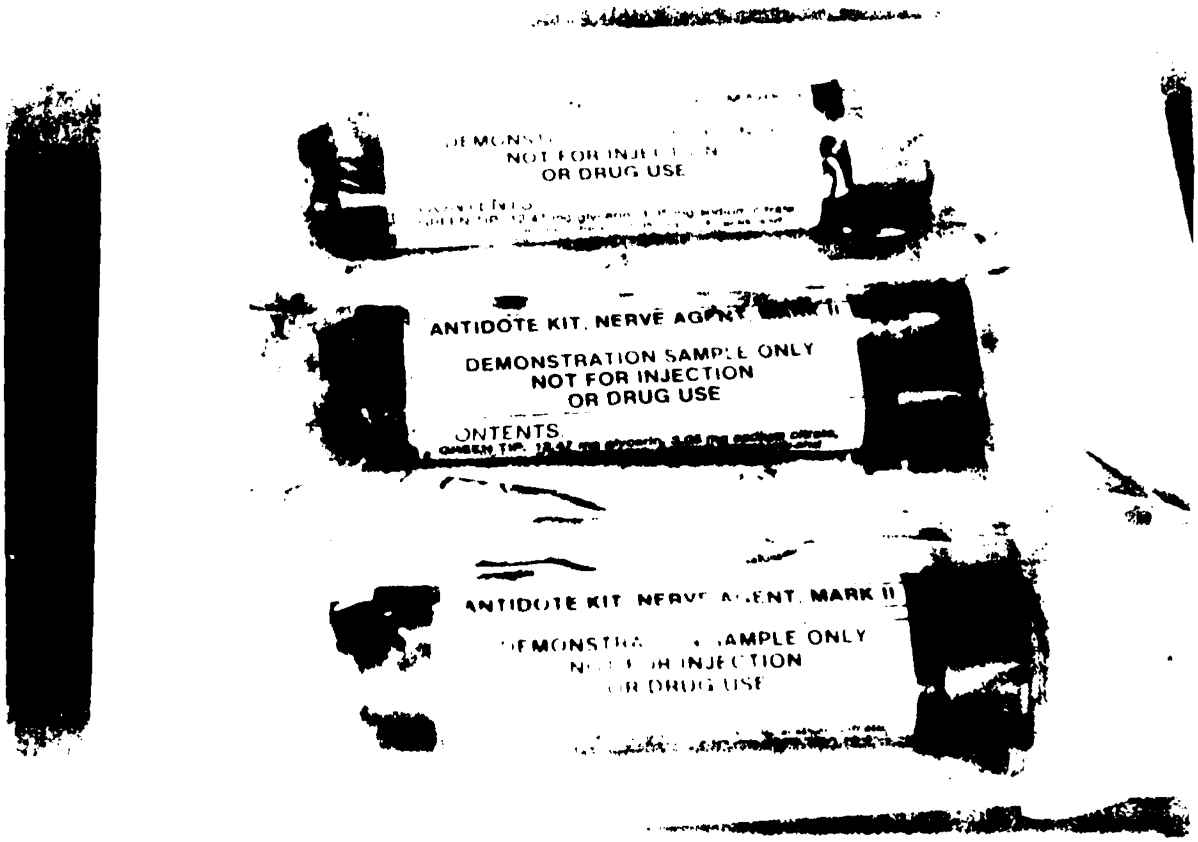


Figure 3. Three examples of the principal malfunction. The atropine barrel on the two upper injectors has come forward and is loose. If a relatively light force is applied to this tip, the needle is triggered (as seen in the third injector) and the contents of the barrel are discharged. The safety caps are securely in place. Soldiers were generally unaware of a problem unless the needle fired.

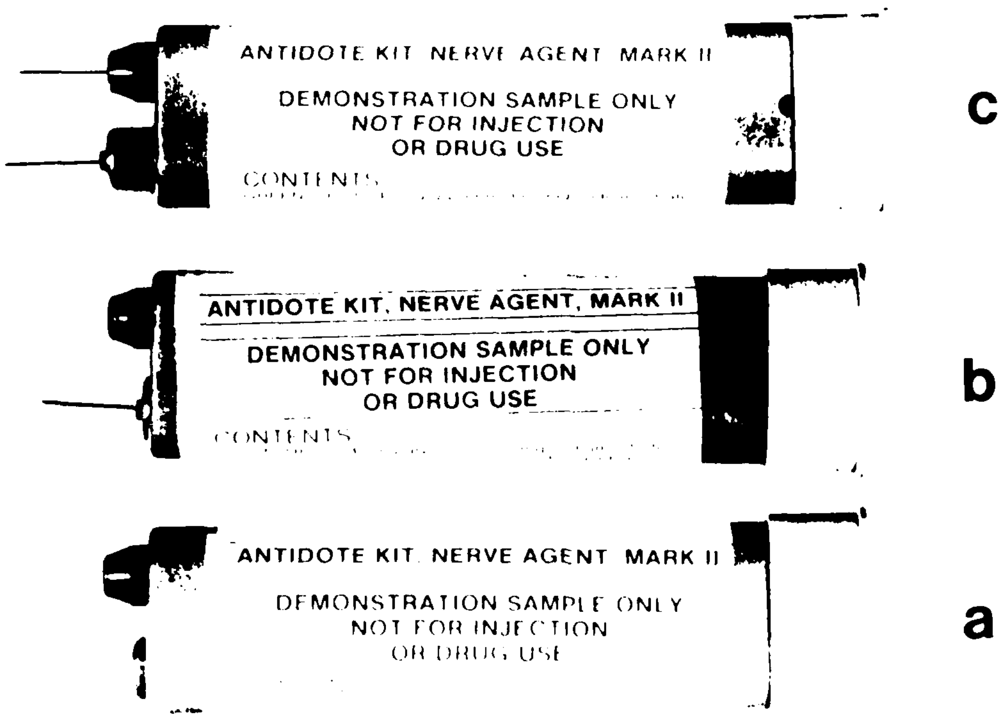


Figure 4. A comparison of the position of the safety caps on a normal injector (a), a malfunctioned injector with the atropine barrel fired (b), and a normal injector after firing (c). The safety cap cannot be replaced on a normally fired injector but remains in place on the malfunctioned injector.

The atropine barrel defect also occurred in all three injectors of one set which traveled to the field site but remained packed away in a duffel bag (Table 9). Although not truely exposed to the field environment this set was subjected to the rough treatment that duffel bags receive, piled into a truck with 40-50 other bags, and transported to and from the field. No such malfunction was reported for injectors in either of the two control groups.

There were no known accidental firings of the 2-PAM-Cl barrel alone. There was also no reliable record of malfunctions leading to the accidental firing of both barrels in the initial inspection (see Unit 6 description above). At USAMBRDL, however, 15 injectors were found to have been fired, including four injectors from the control group (Table 9). The position of the safety caps was not documented.

At least four field exposed injectors were returned with cracked outer casings. These problems were the result of extreme external forces such as a tracked vehicle driving over one soldier's web gear (and injectors) after he had set it down on the ground.

A higher incidence of excessive force to activate the injectors was noted in controls than in field exposed injectors (Table 9).

Deficient volumes from the atropine barrel were noted in all groups. The incidence of volumes below specifications for either barrel was not significantly different between groups (Table 9).

Table 9. Distribution of Malfunctions between Control and Field Exposed Injectors.*

Category	Field Exposed	**Unexposed to Field	Shipping Controls	Reference Controls
INSPECTION AFTER EXPOSURE/CONTROL PERIOD				
loose atro barrel	33 (2.1)	3 (1.2)	0	0
atro needle fired	10 (0.6)	0	0	0
cracked casing	4 (0.2)	0	0	0
USAMBRDL INSPECTION & ENGINEERING TESTS				
injector fired	10 (0.6)	1 (0.4)	1 (1.6)	3 (5.0)
high force to fire	88 (5.9)	9 (4.0)	5 (9.8)	7 (12.5)
atro vol deficient	52 (3.7)	5 (1.9)	1 (2.0)	2 (3.8)
2-PAM vol deficient	15 (1.1)	2 (1.0)	0	0
loose safety pin	164 (11.0)	27 (10.7)	10 (18.8)	13 (21.7)
NO DEFECTS NOTED	1184 (76.5)	209 (82.9)	42 (70.0)	35 (58.0)
UNKNOWN OUTCOME	23	0	0	0
TOTAL (1920)	1548	252	60	60

* percentage of the tested/examined sample exhibiting the malfunction is given in parentheses

** injectors which were issued to units but which were returned without wear

The safety pin (within the safety cap) was noted to be loose in a high incidence of cases (11%), distributed throughout the test groups (Table 9). In eight injectors there was a safety pin defect which could directly affect function. These were categorized as a broken or stuck safety pin (injector would not fire) and the absence of a screw securing the safety pin; one of the broken safety pin defects occurred in a control group.

4. Relationship of Job Activity to the Atropine Barrel Malfunction. There was a significant difference in the distribution of the atropine barrel malfunction between units (Table 10). This does not appear to be related to activity of the foot soldier because one of the lowest incidences was seen in the Infantry units. When listed by individual injector, the trend of a relationship to driving in the field becomes obvious (Table 11). This was further

Table 10. Distribution of Atropine Barrel Malfunction by Unit.

Unit	Injectors Tested	Injectors Malfunctioned	Malfunction Rate overall	Malfunction Rate by sets
1 BDE HHC	201 (67)	6 (3)	3.0 %	4.5 %
2 ENGR	237 (79)	15 (9)	6.3	11.4
3 ADA	186 (62)	5 (3)	2.7	4.8
4 FA	225 (75)	10 (8)	4.4	10.7
5 MI	144 (48)	2 (2)	1.4	4.2
6 INF	532 (174)	8 (5)	1.5	2.9
Totals	1525 (505)	46 (30)	3.0 %	5.9 %

Table 11. Summary of Injectors with the Atropine Barrel Malfunction (defect 1 = loose barrel; defect 2 = fired).

Injector	Unit/Subj		Rank	MOS	Defect 1	Defect 2	*Job and/or possible relation to handling
0115					+		
0116	3	223	E2	16S	+		KEPT IN DUFFEL BAG
0117					+		
0156	3	194	E4	16R		+	GUNNER/JUMPS DOWN 4'
0159	3	197	E5	16R	+		DRIVER, 5 TON TRUCK
0273	4	312	E2	13F	+		----
0308	4	290	E3	13F	+		LOTS OF LOW CRAWLING
0334	4	274	O4	---	+		LOTS OF DRIVING
0342					+		
0399	4	302	E4	13F	+		DURING LOW CRAWL
0393	4	306	E4	13F	+		----
0407					+		
0417	4	310	E5	13F		+	----
0463	4	323	E3	13F	+		M113 (APC) DRIVER
0466	4	325	E3	13F	+		----
0548	8	399	E2	11B	+		DRAGON GUNNER
0715	6	410	E2	11C	+		DRIVER 1/4 TON
0716						+	
0784	1	124	E4	11B	+		BDE SUPPLY (DRIVING)
0786					+		
0794	1	126	E2	11B	+		BDE S-3 DRIVER
0795					+		
0892	1	140	E8	76Z	+		BDE SUPPLY
0893					+		
1251	5	551	E4	96R	+		----
1372	5	572	E6	96R	+		DRIVER
1565	7	538	E4	11B		+	ARMORER/FIRED DURING
1566						+	FALL WHILE RUNNING
1588	7	536	E3	31K	+		----
1600	6	431	E3	31K	+		----
1601					+		
1803	2	14	E4	62J		+	HEAVY EQUIP OPERATOR
1807	2	21	E2	62J		+	BULLDOZER & BUCKET
1808						+	LOADER OPERATOR
1817	2	13	E3	12B		+	MESS TRUCK DRIVER
1819					+		
1820	2	32	E3	62J	+		HEAVY EQUIP OPERATOR
1821					+		
1925	2	55	E3	12B	+		882 DRIVER
2063	2	18	E4	62J	+		HEAVY EQUIP OPERATOR
2074	2	45	E4	12B	+		DRIVER
2076					+		
2098					+		
2099	2	1	E4	76Y	+		DRIVER 2-1/2 T SUPPLY
2100						+	
2142	2	44	E3	12B	+		DRIVER

*the actual occurrence of a malfunction was only detected in a few cases where the needle came through the pouch

pursued with a breakdown into three principal job categories within the engineering unit. The most reliable information was available for this unit and the incidence of malfunction was high. Categorized as driver or frequent passenger (e.g. company commander), stationary adminstrative or mechanical jobs, and active foot soldier, there was a very clear and significant association between the occurrence of the atropine barrel malfunction and driving (Table 12).

Table 12. Crosstabulation of Principal Activity and Atropine Barrel Malfunction in Unit 2 (Chi square = 30.2, p < 0.001).*

Principal Activity	Malfunct	No malfunct	row total
Driving/Driver	15 (9)	57 (15)	72 (24)
Admin & Mechanic	0	60 (20)	60 (20)
Foot soldier	0	105 (35)	105 (35)
column total	15 (9)	222 (70)	237 (79)

*number of injectors; number of soldiers given in parentheses

5. Serviceability of the Injector Wrapper. The outer covering on the injectors became quickly worn during the field testing (Figure 5). Within a few days the injector coverings had lost their clear and smooth appearance and by the end of the test the wrappers were worn thin and holes developed (Table 13). The packaging was not sealed closely enough to prevent manipulation or accidental dislodgement of the safety caps. These could be moved far enough to allow firing of the device without removal from the package (Figure 6).

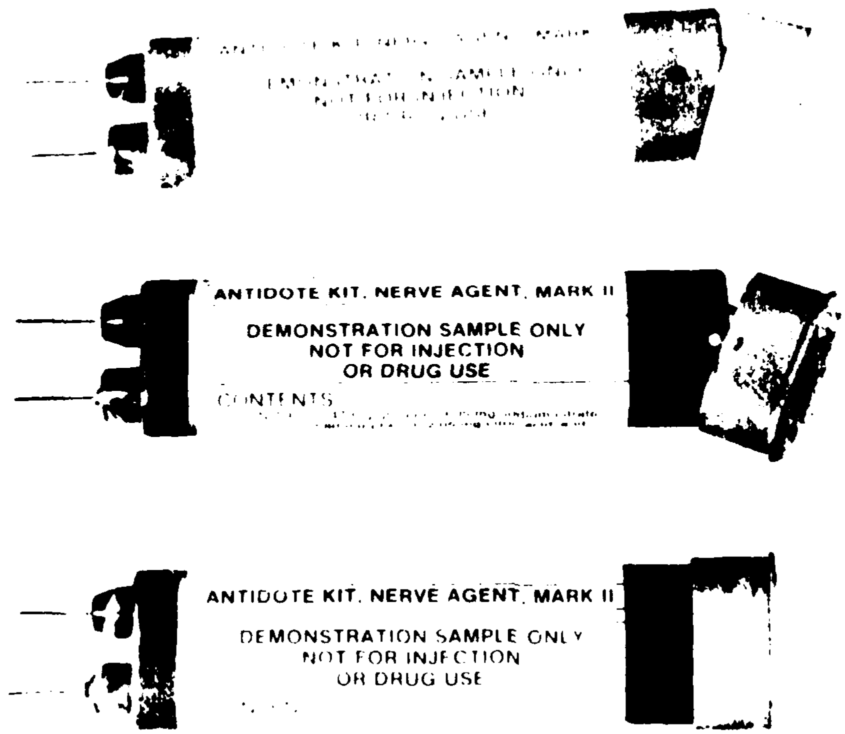
Figure 5. The typical dirty and worn appearance of injector packaging after 18 days exposure to field conditions in an ammunition pouch. This set was carried by a tracked vehicle driver.

Table 13. Wear on Plastic Wrapping by Unit, Rank & CMF.*
(Percentages within rows are given in parentheses).

Category	No damage	Punctured	Unsealed**	Torn
UNIT				
1 HHC	5 (2.5)	10 (5.0)	187 (92.6)	0
2 ENGR	21 (8.8)	136 (56.7)	76 (31.7)	7 (2.9)
3 ADA	63 (30.7)	79 (38.5)	54 (26.3)	9 (4.4)
4 FA	117 (51.5)	51 (22.5)	58 (25.6)	1 (0.4)
5 MI	51 (34.7)	46 (31.3)	50 (34.0)	0
6 INF	37 (6.8)	60 (11.0)	440 (80.6)	9 (1.6)
RANK				
PV1-PFC	96 (16.6)	114 (19.7)	354 (61.2)	14 (2.4)
SP4	81 (16.7)	135 (27.9)	265 (54.8)	3 (0.6)
SGT-SSG	87 (27.9)	76 (24.4)	146 (46.8)	3 (1.0)
SFC-SGM	11 (13.9)	28 (35.4)	38 (48.1)	2 (2.5)
WO1-COL	19 (17.1)	29 (26.1)	59 (53.2)	4 (3.6)
CMF				
11 Inf	26 (5.5)	35 (7.4)	406 (86.4)	3 (0.6)
16 ADA	51 (35.9)	40 (28.2)	42 (29.6)	9 (6.3)
13 FA	89 (54.6)	37 (22.7)	36 (22.1)	1 (0.6)
12 Engr	17 (11.6)	83 (56.5)	41 (27.9)	6 (4.1)
31 Commo	17 (17.5)	26 (26.8)	52 (53.6)	2 (2.1)
96 MI	14 (19.7)	19 (26.8)	38 (53.5)	0
63 Mech	6 (11.8)	23 (45.1)	21 (41.2)	1 (2.0)
76 Supply	11 (22.0)	18 (36.0)	21 (42.0)	0
62 Constr	1 (2.4)	24 (57.1)	17 (40.5)	0
54 Chem	5 (20.8)	4 (16.7)	15 (62.5)	0
Other	25 (19.8)	41 (32.5)	60 (47.6)	0

* injectors not exposed to field conditions are excluded
** larger-than-puncture openings (0.5 - 3.0 cm)

6. Soldier Interviews. When asked to comment on the convenience or inconvenience of the autoinjectors, 138 out of 151 soldiers (91.4%) simply indicated that the size of the autoinjector was "about right" and 136 out of 148 soldiers (91.9%) claimed that the autoinjectors were



<u>Figure</u> <u>6</u>. Three demonstrations that the safety cap can be removed or dislodged sufficiently to arm the injectors without removal from the wrapper.

comfortable when carried in the ammunition pouch. More informative suggestions and comments came with additional proding by the interviewers and these are summarized in Table 14. The comments about problems relate to specific individual requirements (e.g. small waist, special equipment, cramped quarters in a turret). Most respondents could not think of a better location for the injectors than the ammunition pouch mounted on the web belt. The comment: "I just put it on my web belt and forgot about it; I didn't even notice it" was typical.

Table 14. Summary of Soldier Comments and Suggestions.*

What kinds of problems did you have or would you anticipate with the present arrangement?

- 3 - not enough room on the belt because of small waist
- 2 - may confuse injectors with magazines (need to be able to distinguish the pouches)
- 2 - in the way of my arm and/or weapon
- 1 - in the way of where I carry my binoculars
- 1 - should put in mask carrier because sometimes I take off my web gear (APC driver)

What would be a better location for the injectors?

- 11 - should go in the mask carrier
- 7 - carry on LBE suspenders
- 4 - carry on the outside of the mask carrier
- 2 - carry on leg

What sorts of modifications did you try?

- 17 - not carried, left in ruck or duffel bag
- 6 - carried only the injector pouch and one ammo pouch
- 4 - carried only the injector pouch (no ammo pouches)
- 3 - carried on the left side
- 2 - not carried, kept in vehicle
- 1 - carried on the suspenders, free hanging (not very convenient)

---

*number of responses are indicated

DISCUSSION

The atropine barrel malfunction was a significant finding in this test. In less than three weeks in an environment with rough terrain, 5.9% of the soldiers had one or more failures within their sets of three injectors. The incidence of malfunction was 3.0% of all injectors which were exposed to field conditions. Unless this failure was related to a weakness in these specific injectors, the incidence of malfunction could be assumed to increase linearly over time.

This defect actually progressed to the stage of accidental firing in only ten of the 46 malfunctioned injectors. The remaining 36 injectors may have still been able to deliver a volume although the atropine barrels were essentially "armed" even with the safety cap in place. For injectors with a loose atropine barrel it is not clear that the atropine barrel would have fired on contact demand.

Although the atropine barrel malfunction occurred 46 times when handled by soldiers, no such malfunctions occurred in the controls. In 120 control injectors, a similar failure rate would result in approximately three malfunctions which is also within reasonable limits of probability ($p<0.05$) for no malfunctions to occur. However, the association between specific soldier activities (driving) and the occurrence of the malfunction supports the indication that this was a problem related to field exposure.

Other functionally significant problems were clearly distributed between control and field-exposed injectors: deficient atropine barrel volumes, excessive activation forces, and loose safety pins. Because of the distribution of these defects, these are probably manufacturing problems and are not related to soldier handling or field exposure. The incidence of volume deficient 2-PAM-Cl barrels was too low to detect in the control injectors but at least some of the 2-PAM-Cl barrel malfunctions had broken ampules and cracked casings and these were clearly associated with soldier handling. Fifteen injectors were found to be fired in the USAMBRDL inspection but, since these included three injectors in the reference controls and no accidental firings of both needles occurred during the field test, this occurrence remains unexplained.

The plastic wrappers were clearly inadequate for long term (i.e. three weeks or greater) exposure to field conditions and the majority of these coverings were unsealed by the end of this test. The coverings also were not sealed tightly enough to prevent arming the injectors without removal from the plastic.

Some soldiers stated that they were disturbed by the possibility of an accidental triggering of their injectors, especially the ones which had seen a dramatic injector demonstration. This made them reluctant to carry the injectors in the field. If a demonstration of the injector was enough to have this effect, then the occurrence of even

a single malfunction, where a needle penetrates the bottom of a soldier's ammunition pouch, could be expected to pose a significant problem in terms of soldier compliance in carrying the injectors. This was prevented in the engineer company, which had a predominance of the accidental firings (4 soldiers), by aggressive enforcement of the test. The other units with accidental firings were either scattered into small subunits and word of the failures did not get around (e.g. field artillery), or word did get around and compliance was poor (e.g. air defense artillery).

This study demonstrated the importance of field testing new products with soldiers in a real field environment as an adjunct to the standard laboratory testing. The finding of a significant injector malfunction associated with motorized travel in rough terrain was not an anticipated finding.

Appendix A-1. Personal Data/Injector Handreceipt.

September 1985

DUAL CHAMBER AUTOINJECTOR SYSTEM, MARK II

DEVELOPMENTAL TEST (FIELD) QUESTIONNAIRE

Personal Data Summary

Last Name________________ First Name____________ MI________

Rank____________ Social Security Number______________________

Organization____

Duty Phone__________ Duty MOS/Position______________________

Assigned Subject Identification Code___________________________

Autoinjector ID Number	Date Issued	Date Turn-In	Condition at Turn-In

I acknowledge receipt of three (3) each Autoinjectors, and one (1) each Case, Small Arms Ammunition.

(Date)__________ (Signature)__________________________

Appendix A-2. Soldier Opinions Questionnaire.

September 1985

DUAL CHAMBER AUTOINJECTOR SYSTEM, MARK II

DEVELOPMENTAL TEST (FIELD) QUESTIONNAIRE

Subject Identification Code______________

1. Is the size of the autoinjector:

____Too bulky ____Too heavy ____Too thick

____Too long ____Too wide ____About right

2. Was the autoinjector comfortable while carrying it?

____Yes ____No

3. Did you have any problems with the autoinjector such as damage of any sort? (Specify below)

____Yes ____No

4. During the course of this exercise, was your equipment exposed to any adverse conditions? (Check as applicable.)

____ rain ____ fog ____ fuel ____ other (Specify)

____ humidity ____ dust ____ lubricant ______________

5. Do you have any other comments or suggestions? (Specify below)

____Yes ____No

____

____

Appendix A-3. Injector External Condition Checklist.

Inspection Checklist September 1985

Field Developmental Test

Dual Barrel Automatic Injector, Mark II

Insp. by:____________________ Date:__________ Autoinjector ID No.:________

Inspection relative to:____
(phase of field developmental testing)

(Use reverse side for explanatory information)

Wrapper:..................Missing.................................☐
Torn....................................☐
Unsealed................................☐
Punctured...............................☐

Black Tip:..................Needle protrudes from tip...............☐

Green Tip:..................Needle protrudes from tip...............☐
Green tip protrudes from case...........☐

Safety Cap:...............Missing.................................☐
Loose...................................☐

Case:......................Cracked.................................☐
Broken..................................☐
Open....................................☐

Loose material (specify):...In bag..................................☐
In case.................................☐

Leakage (specify location):...☐

Component (specify):........Loose...................................☐
Missing.................................☐

Label:.....................Torn or missing.........................☐
Illegible or mutilated..................☐

Other evidence of unserviceability or damage (specify)..............☐

Appendix A-4. Sample Engineering Test Datasheet.

njector lumber:	Firing Force: (2-8 lbs)	AtroPen Volume (.66-.80ml)	ComboPen Volume: (1.8-2.2ml)	AtroPen Discharge ≤ Immed?		ComboPen Discharge >4 sec.?		AtroPen NEL 0.75-0.875		ComboPen NEL .709-.905	Comments:
2089	5.0	5.76 5.02 .74	6.42 4.45 1.97	✓		1.64		✓		✓	
2148	4.5	3.77 3.04 .73	4.49 2.50 1.99	✓		1.82		✓		✓	
2147	4.0	4.42 3.77 .65	6.42 4.49 1.93	✓		1.57		✓		✓	? low
2061	4.0	5.16 4.42 .74	4.58 2.50 2.08	✓		1.84		✓		✓	
2146	4.75	5.83 5.16 .67	6.57 4.58 1.99	✓		1.65		✓		✓	
2059	4.5	3.86 3.14 .72	4.53 2.50 2.03	✓		1.73		✓		✓	
1977	6.0	4.60 3.86 .74	6.46 4.53 1.93	✓		1.56		✓		✓	
1975	5.5	5.31 4.60 .71	4.47 2.50 1.97	✓		1.81		✓		✓	

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